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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,934	02/22/2007	Toshihiko Miyamoto	2006_1252A	5698

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EXAMINER	
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ART UNIT	PAPER NUMBER
4112	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,934	MIYAMOTO ET AL.	
	Examiner	Art Unit	
	DANIELLE HENKEL	4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office action on the 10/587934 application filed on February 22, 2007.

2. Claims 1-10 are pending and have been fully considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by MIYAMOTO (US 6197574).

a. With respect to claims 1 and 4, MIYAMOTO teaches a bacterium detector comprising a hollow cylindrical container with an opening and a cover (cap) that can be freely inserted (engaging) into (forms closed system) and detached from the opening (Column 20, lines 47-49). The disclosed container is used for incubation (space for culturing) (Column 21, lines 46-48). The disclosed cap allows for the maintenance of a tight-sealed system (hermetically sealed) (Column 25, line 30) and includes a microorganism collecting member (sample collecting member) extending vertically to the opening of the container (capable of being inserted and

drawn from) (Column 21, lines 12-15). MIYAMOTO teaches the cap contains (cap is hollow) a bag-shaped member or vessel (storage space) enclosing (not in contact with collector) medium for the incubation of specific microorganisms (Column 20, lines 51-53). The medium storage space is released into the container when a strong compressing force outside the cover breaks the vessel resulting in the microorganism collecting part being dipped into the medium (Column 22, lines 13-20). MIYAMOTO also teaches the upper end of the cap has a second bag shaped vessel which encloses a disinfectant (Column 20, lines 54-57). The second storage space is also broken by applying a sufficient force from outside the cover causing the release of disinfectant into the container causing the mixture of the microorganisms to be mixed with the disinfectant (Column 23, lines 4-13). MIYAMOTO also discloses the cover may be constituted from soft plastics such as soft resin (synthetic resin) and is connected to the container by a screw thread or bayonet (engaging portion) (Column 23, lines 49-55). The cap includes a partition member with holes (capable of communicating with container) (Column 20, lines 63-64). MIYAMOTO teaches the cap has a partition member between the first and second liquid enclosing bag members (independent chambers) and a partition between the first bag member and the opening of the cap (Column 20, line 61- Column 21, line 2). MIYAMOTO also discloses the first and second bag members are opened by applying a strong compressing force to the outside of the cap allowing the liquid to be

released through holes (opening forming part) in the partition members (Column 22, lines 13-20).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

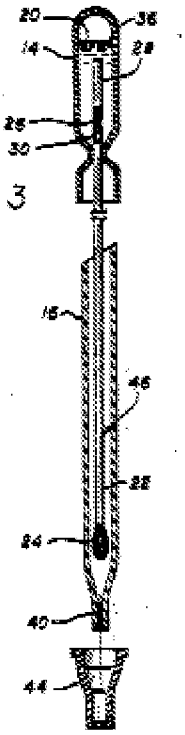
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 3, 5, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over MIYAMOTO (US 6197574) as applied to claims and in view of NASON (US 5266266).

a. With respect to claim 2, MIYAMOTO does not disclose the opening-forming part of the partition member comprising a stick like protrusion. However, NASON teaches a specimen test unit with a break-off nib (protrusion) at the rear end of the specimen collecting swab (axial direction) where the swab and break off nib (opening forming part) are connected at a reduced diameter score (thin walled fragile part) with a central bore (opening) located within (Column 4, lines 35-42, Figure 3). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the bacterium detector of MIYAMOTO to include the break off nib opening forming part of NASON. The motivation would have been NASON teaches the disclosed device allows for reagent delivery without the use of expensive and dangerous glass ampoules or

difficult and unreliable rupturable plastic compartments (Column 1, line 62-Column 2, line 19).

Fig. 3



b. With respect to claim 3, MIYAMOTO teaches the cap is hollow and made of synthetic resin as addressed above. NASON teaches the use of a resiliently deformable plastic material as the housing (wall) when manually bent (external force) is effective to bend the rod portion of the nib (abutting the wall against the protrusion) relative to the shaft (in perpendicular axis) of the swab. Breaking off the nip creates an opening in the reduced diameter portion of the housing (Column 5, lines 48-60).

c. With respect to claim 5, NASON teaches the nib is an integral portion of a seal (partition) in the cap (hollow container side) that allows for the rear end of the swab to be seated (movably fitted) therein (concave)

(Column 2, lines 61-65). This break off nib of NASON occurs between the swab shaft and break off nib as the device of NASON includes only one reagent chamber. However in the combination of NASON with the two chamber detector of MIYAMOTO it would be an obvious substitution to use the break off nib with the concave for the swab shaft of NASON at the second partition as well.

d. With respect to claim 8, NASON teaches the break off nib (stick like protrusion) has an upper rod segment (cross section with vertical length approximately equal to horizontal) formed as a continuation of the swab shaft (Column 4, lines 35-40, Figure 4).

e. With respect to claim 9, NASON discloses the cap body from the closed end to the seal collar (second wall portion) has a cylindrical geometry (cross section vertical length approximately equal to horizontal) (Column 4, lines 58-60).

f. With respect to claim 10, MIYAMOTO teaches a cap member is located on the top end (second wall portion) of the cover member (cap body) (Column 35, lines 47-52) that can be slid to the side of the container (movable) (Column 36, line 36-37). MIYAMOTO does not explicitly disclose this cap is a protecting sheath, however, NASON discloses the use of an over cap that closes an outlet (protecting sheath) (Column 8, lines 15-18). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the cap member of the bacterium detector of MIYAMOTO to include the protecting overcap of NASON. The

motivation would have been NASON discloses the overcap prevents the flow of liquid through a tip (opening of break off nib) until it is removed (Column 8, lines 30-33).

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over MIYAMOTO (US 6197574), in view of NASON (US 5266266) as applied to claims 2, 3, 5 and 8-10 above, and further in view of MATKOVICH (US 4731061).

a. With respect to claims 6 and 7, neither MIYAMOTO nor NASON explicitly disclose the first wall of the cap body and the stick like protrusion having a cross sectional shape wherein the vertical and horizontal lengths are unequal. However, MATKOVICH teaches a plastic closure and applicator cap in which the tip portion of the cap body has an extremity (wall) that is preferably flat (cross section vertical and horizontal lengths unequal) (Column 4, lines 57-60). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the cap member of the bacterium detector of MIYAMOTO with the break off tip of NASON with the flat shape of MATKOVICH. The motivation would have been that MATKOVICH discloses the flattened shape is easily manually broken in the intended manner without special tools required (Column 2, lines 40-45). NASON In the cap disclosed by MATKOVICH the cap and the break off tip are the same device, however, in combining the flattened shape of MATKOVICH with the break off tip device combination of MIYAMOTO and NASON it would be an obvious substitution to make both the cap and the break off tip with a flattened shape.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. NASON (US 5879635) discloses a dispenser for dispensing multiple reagents in separate chambers with a dual nib sealing the chambers that must be displaced to allow the reagents to mix.

b. NASON (US 6248294) discloses a diagnostic test unit for collection of a biological specimen including a break off tip that allows a test reagent to enter a housing with a swab containing the specimen.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 7:30am-5pm, Alternate Fridays: 7:30am-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara Gilliam can be reached on 571-272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBH

/Barbara L. Gilliam/
Supervisory Patent Examiner, Art Unit 4128